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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,083	07/22/2004	Jens Lerchl	12810-00046-US	4008

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EXAMINER

MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/502,083

Applicant(s)

LERCHL ET AL.

Examiner

Mohammad Meah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/6/06, 10/28/04 10/27/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant, on date 11/16/2005 elected with traverse Group I (claims 1-4, 6-11 and 22-25) for examination.

Election/Restriction

Applicant, on date 11/16/2005 elected with traverse Group I (claims 1-4, 6-11 and 22-25), drawn to DNA encoding elongase, vector, and plants as transformed organism. Groups II-IV (claims 5, 12-21) of election/restriction-office action of date 10/17/2005 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election with traverse of group I (claims 1-6, 6-11 and 22-25), in the reply filed on 10/14/2005 is acknowledged.

The traversal is on the ground(s) that unity of invention exists between the groups. This is not found persuasive as explained below and therefore Groups II-IV (claims 5, 12-21) of election/restriction-office action of date 10/17/2005 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicants arguments of 1.) All claims belonging groups I-IV is directed to "same general inventive concept" and 2.) The claims are linked by a special technical feature because applicant's elongase possess special technical feature are answered as follows:

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Applicants argument of the claims are linked by a special technical feature is not persuasive because Mukerji et al. (us patent 6913916) teach gene encoding elongase that elongate PUFA.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgement is made of applicant's PCT priority date based on application filing date of 01/13/2003 of PCT/EP03/00221 and foreign applications Germany 10203713.2 filed on date 01/30/2002 and Germany 1020560.2 filed on date 02/11/2002.

Objections

Claims 1 and 9, C_{20:50}^{Δ 5,8,11,14, 17} should this be C_{20:5}^{Δ 5,8,11,14, 17} ?

Claim Rejections

35 U.S.C 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

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use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-11 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules encoding an elongase from any source and vectors & host cells encompassing said DNAs. The specification teaches the structure of only a single representative species of such DNAs. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding elongase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-4, 6-11 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA of SEQ ID NO: 1 does not reasonably provide enablement for any DNA that is 50% homologous with DNA encoding protein having amino acid sequence of SEQ ID

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NO: 2 or any DNA encoding an elongase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and for use the invention commensurate in scope with these claims.

Claims 2-4 are so broad as to encompass any vectors or host cells or DNA encoding a protein which has 50% identity to SEQ ID NO: 2 and encodes a protein having elongase activity while claims 1, 6-11 and 22-25 are so broad as to encompass any DNA which encodes any elongase. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number DNAs that encode amino acids sequences of proteins broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleic acid that encodes an amino acid sequence of only one elongase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of

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success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass any nucleic acid encoding a protein having 50% identity to SEQ ID NO: 2 or any nucleic acid encoding any elongase because the specification does not establish: (A) regions of the protein structure which may be modified without effecting elongase activity; (B) the general tolerance of elongase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any elongase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including DNA that encode an enormous number of modifications of DNA encoding protein having amino acid sequence of SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of elongase genes, having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly,

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extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

CLAIM Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6-11 and 22-23 are rejected under USC 102(a) by as being anticipated by Wallis et al. (Trends in Biochemical Sci., 2002, vol. 27, pp 467473). Wallis et al. teaches biosynthetic genes encoding variety of elongases, vectors, organisms and elongation of C-18 fatty acid to at least two double bonds to at least four double bonds but do not elongate C₂₀ PUFAs.

Claims 1, 6-11 and 22-23 are rejected under USC 102(e) by as being anticipated by Napier et al. (US 2005/0089981 A1). Napier et al. teaches gene

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encoding elongase from fungi such as mortierella or scizochytrium), vector, organisms and elongation of C-18 fatty acid to at least two double bonds to at least four double bonds, wherein γ -linolenic acid ($C_{18:3}^{\Delta 6,9,12}$) is not elongated .

Claims 1, 6-11 and 22-23 are rejected under USC 102(e) by as being anticipated by Mukerji et al. (US6913916 B1). Mukerji et al. teaches gene encoding elongase from fungi such as mortierella alpina), vector, organisms and elongation of C-18 fatty acid having at least two double bonds to at least four double bonds.

Applicants isolated nucleic acid comprising the nucleic acid sequence of SEQ ID NO: 1 appears to be novel. Therefore claims limited to isolated nucleic acid comprising the nucleic acid sequence of SEQ ID NO: 1 or encoding the elongase of SEQ ID NO: 2 would be allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed M. Y. Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

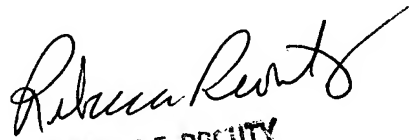
Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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